Claims

1. A method for stimulating an immune response in a subject comprising administering to a subject in need of immune stimulation an agent of Formula I, and an antibody or antibody fragment, in an amount effective to stimulate an immune response.

2. The method of claim 1, wherein the immune response is antibody dependent cell-mediated cytoxicity.

3. The method of claim 1, wherein the antibody or antibody fragment is an antibody.

4. The method of claim 1, wherein the antibody or antibody fragment is an anti-HER2 antibody.

5. The method of claim 4, wherein the anti-HER2 antibody is trastuzumab.

6. The method of claim 1, wherein the antibody or antibody fragment is an anti-CD20 antibody.

7. The method of claim 6, wherein the anti-CD20 antibody is rituximab.

8. The method of claim 1, wherein the antibody or antibody fragment is administered in a sub-therapeutic dose.

9. The method of claim 1, wherein the agent of Formula I is administered in a route of administration different from that of the antibody or antibody fragment.

10. The method of claim 1, wherein the agent of Formula I is administered orally and the antibody or antibody fragment is administered by injection.

11. The method of claim 1, wherein the agent of Formula I is administered prior to the antibody or antibody fragment.

12. The method of claim 11, wherein the agent of Formula I is administered 30 minutes to 8 hours prior to the antibody or antibody fragment.

13. The method of claim 11, wherein the agent of Formula I is administered 1 to 7 days prior to the antibody or antibody fragment.

14. The method of claim 1, wherein the agent of Formula I is administered substantially simultaneously with the antibody or antibody fragment.

15. The method of claim 1, wherein the agent of Formula I is administered after the antibody or antibody fragment.

16. The method of claim 15, wherein the agent of Formula I is administered 30 minutes to 8 hours after the antibody or antibody fragment.

17. The method of claim 15, wherein the agent of Formula I is administered 1 to 7 days after the antibody or antibody fragment.

18. A method for stimulating an immune response in a subject having or at risk of having cancer comprising

administering to a subject in need of immune stimulation an agent of Formula I, and an antigen, in an amount effective to stimulate an antigen-specific immune response.

19. The method of claim 18, wherein the subject is a subject having cancer.

20. The method of claim 18, wherein the cancer is selected from the group consisting of a lymphoma or leukemia.

21. The method of claim 18, wherein the agent of Formula I is administered in a route of administration different from that of the antigen.

22. The method of claim 18, wherein the agent of Formula I is administered in a dose of greater than 10^{-8}M.

23. The method of claim 18, wherein the subject has not undergone an anti-cancer therapy selected from the group consisting of surgery, radiation and chemotherapy.

24. A method for stimulating an immune response in a subject comprising

administering to a subject in need of immune stimulation an agent of Formula I, and an antigen, in an amount effective to stimulate an antigen-specific immune response,

wherein the agent of Formula I is administered at a concentration of greater than 10^{-8}M.

25. The method of claim 1 or 24, wherein the subject is a subject having or at risk of developing cancer.

26. The method of claim 25, wherein the cancer is selected from the group consisting of a carcinoma and a sarcoma.

27. The method of claim 18 or 25, wherein the cancer is selected from the group consisting of basal cell carcinoma, biliary tract cancer; bladder cancer; bone cancer; brain cancer; breast cancer; cervical cancer; choriocarcinoma; CNS cancer; colon and rectum cancer; connective tissue cancer; cancer of the digestive system; endometrial cancer; esophageal cancer; eye cancer; cancer of the head and neck; gastric cancer; intra-epithelial neoplasm; kidney cancer; larynx cancer; leukemia; acute myeloid leukemia; acute lymphoid leukemia; chronic myeloid leukemia; chronic lymphoid leukemia; liver cancer; small cell lung cancer; non-small cell lung cancer; lymphoma; Hodgkin's lymphoma; Non-Hodgkin's lymphoma; melanoma; myeloma; neuroblastoma; oral cavity cancer; ovarian cancer; pancreatic cancer; prostate cancer; retinoblastoma; rhabdomyosarcoma; rectal cancer; renal cancer; cancer of the respiratory system; sarcoma; skin cancer; stomach cancer; testicular cancer; thyroid cancer; uterine cancer; and cancer of the urinary system.

28. The method of claim 18 or 25, wherein the cancer is selected from the group consisting of bladder cancer, breast cancer, colon cancer, endometrial cancer, head and neck cancer, leukemia, lung cancer, lymphoma, melanoma, ovarian cancer, prostate cancer and rectal cancer.

29. The method of claim 18 or 25, wherein the cancer is a metastasis.

30. The method of claim 1, 18 or 24, wherein the subject is a subject having or at risk of developing an infectious disease.

31. The method of claim 30, wherein the infectious disease is selected from the group consisting of a bacterial infection, a mycobacterial infection, a viral infection, a fungal infection and a parasitic infection.

32. The method of claim 31, wherein the bacterial infection is selected from the group consisting of an E. coli infection, a Staphylococcal infection, a Streptococcal infection, a Pseudomonas infection,

Clostridium difficile infection, Legionella infection, Pneumococcus infection, Haemophilus infection, Klebsiella infection, Enterobacter infection, Citrobacter infection, Neisseria infection, Shigella infection, Salmonella infection, Listeria infection, Pasteurella infection, Streptobacillus infection, Spirillum infection, Treponema infection, Actinomyces infection, Borrelia infection, Corynebacterium infection, Nocardia infection, Gardnerella infection, Campylobacter infection, Spirochaeta infection, Proteus infection, Bacteriodes infection, H. pylori infection, and anthrax infection.

33. The method of claim 31, wherein the infectious disease is a mycobacterial infection selected from the group consisting of tuberculosis and leprosy.

34. The method of claim 31, wherein the viral infection is selected from the group consisting of an HIV infection, a Herpes simplex virus 1 infection, a Herpes simplex virus 2 infection, cytomegalovirus infection, hepatitis A virus infection, hepatitis B virus infection, hepatitis C virus infection, human papilloma virus infection, Epstein Barr virus infection, rotavirus infection, adenovirus infection, influenza A virus infection, respiratory syncytial virus infection, varicella-zoster virus infections, small pox infection, monkey pox infection and SARS infection.

35. The method of claim 31, wherein the fungal infection is selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

36. The method of claim 31, wherein the parasite infection is selected from the group consisting of amebiasis, Trypanosoma cruzi infection, Fascioliasis, Leishmaniasis, Plasmodium infections, Onchocerciasis, Paragonimiasis, Trypanosoma brucei infection, Pneumocystis infection, Trichomonas vaginalis infection, Taenia infection, Hymenolepsis infection, Echinococcus infections, Schistosomiasis, neurocysticercosis, Necator americanus infection, and Trichuris trichuria infection.

37. The method of claim 24, wherein the agent of Formula I is administered in a route of administration different from that of the antigen.

38. The method of claim 18 or 24, further comprising administering an adjuvant to the subject.

39. The method of claim 24, wherein the antigen is targeted to a tissue or a cell.

40. The method of claim 18 or 24, wherein the antigen is a cancer antigen.

41. The method of claim 40, wherein the cancer antigen is selected from the group consisting of MART-1/Melan-A, gp100, adenosine deaminase-binding protein (ADAbp), FAP, cyclophilin b, colorectal associated antigen (CRC)--C017-1A/GA733, carcinoembryonic antigen (CEA), CAP-1, CAP-2, etv6, AML1, prostate specific antigen (PSA), PSA-1, PSA-2, PSA-3, prostate-specific membrane antigen (PSMA), T-cell receptor/CD3-zeta chain, and CD20.

42. The method of claim 40, wherein the cancer antigen is selected from the group consisting of MAGE-A1, MAGE-A2, MAGE-A3, MAGE-A4, MAGE-A5, MAGE-A6, MAGE-A7, MAGE-A8, MAGE-A9, MAGE-A10, MAGE-A11, MAGE-A12, MAGE-Xp2 (MAGE-B2), MAGE-Xp3 (MAGE-B3), MAGE-Xp4 (MAGE-B4), MAGE-C1, MAGE-C2, MAGE-C3, MAGE-C4, MAGE-C5).

43. The method of claim 40, wherein the cancer antigen is selected from the group consisting of GAGE-1, GAGE-2, GAGE-3, GAGE-4, GAGE-5, GAGE-6, GAGE-7, GAGE-8, GAGE-9.

44. The method of claim 40, wherein the cancer antigen is selected from the group consisting of BAGE, RAGE, LAGE-1, NAG, GnT-V, MUM-1, CDK4, tyrosinase, p53, MUC family, HER2/neu, p21ras, RCAS1, α-fetoprotein, E-cadherin, α-catenin, β-catenin, γ-catenin, p120ctn, $gp100^{Pmel117}$, PRAME, NY-ESO-1, cdc27, adenomatous polyposis coli protein (APC), fodrin, Connexin 37, Ig-idiotype, p15, gp75, GM2 ganglioside, GD2 ganglioside, human papilloma virus proteins, Smad family of tumor antigens, Imp-1, P1A, EBV-encoded nuclear antigen (EBNA)-1, brain glycogen phosphorylase, SSX-1, SSX-2 (HOM-MEL-40), SSX-1, SSX-4, SSX-5, SCP-1 and CT-7, and c-erbB-2.

45. The method of claim 18 or 24, further comprising treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

46. The method of claim 45, wherein the agent of Formula I and the antigen are administered prior to treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

47. The method of claim 45, wherein the agent of Formula I and the antigen are administered after treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

48. The method of claim 45, wherein the agent of Formula I and the antigen are administered before and after treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

49. The method of claim 18 or 24, wherein the agent of Formula I is administered to the subject prior to the antigen.

50. The method of claim 18 or 24, wherein the agent of Formula I is administered to the subject 30 minutes to 8 hours prior to administration of the antigen.

51. The method of claim 18 or 24, wherein the agent of Formula I is administered to the subject 1 to 7 days prior to administration of the antigen.

52. The method of claim 18 or 24, wherein the immune response is an antigen specific immune response.

53. The method of claim 18 or 24, wherein the agent of Formula I is administered to the subject after administration of the antigen.

54. The method of claim 53, wherein the agent of Formula I is administered to the subject 30 minutes to 8 hours after administration of the antigen.

55. The method of claim 53, wherein the agent of Formula I is administered to the subject 1 to 7 days after administration of the antigen.

56. The method of claim 18 or 24, wherein the immune response is an innate immune response.

57. The method of claim 18 or 24, wherein the immune response is an adaptive immune response.

58. The method of claim 38, wherein the adjuvant is selected from the group consisting of alum, cholera toxin, CpG immunostimulatory nucleic acids, MPL, MPD, and QS-21.

59. The method of claim 45, wherein the agent of Formula I and the antigen are administered prior to and after treating the subject with a therapy selected from the group consisting of surgery, radiation and chemotherapy.

60. The method of claim 40, wherein the cancer antigen is a gene or gene product thereof that has undergone chromosomal alteration.

61. The method of claim 60, wherein the gene product is a RNA or protein gene product.

62. The method of claim 60, wherein the gene or gene product thereof that has undergone chromosomal alteration is selected from the group consisting of gene or gene products associated with activation of quiescent genes, and gene or gene products associated with a novel fusion gene and protein.

63. The method of claim 62, wherein the gene or gene products associated with activation of quiescent genes is selected from the group consisting of *BCL-1 and IgH, BCL-2 and IgH, BCL-6, TAL-1 and TCRδ or SIL, c-MYC and IgH or IgL, MUN/IRF4 and IgH,* and *PAX-5 (BSAP).*

64. The method of claim 62, wherein the gene or gene products associated with a novel fusion gene and protein is selected from the group consisting of *RARα, PML, PLZF, NPM or NuMA*; *BCR and ABL; MLL (HRX); E2A and PBX or HLF; NPM, ALK*; and *NPM, MLF-1.*

65. The method of claim 40, wherein the cancer antigen is a tissue- or lineage-specific antigen.

66. The method of claim 65, wherein the tissue- or lineage-specific antigen is a cell surface protein, epidermal growth factor receptor, cell-associated protein, or a secreted protein.

67. The method of claim 66, wherein the cell surface protein is selected from the group consisting of CD20, CD22, CD52, CD33, CD10 (gp100), CD3/T-cell receptor (TCR), CD79/B-cell receptor (BCR), CD26, Human leukocyte antigen (HLA)-DR, HLA-DP, and HLA-DQ, RCAS1, and Prostate specific membrane antigen.

68. The method of claim 66, wherein the epidermal growth factor receptor is selected from the group consisting of EGFR (HER1 or erbB1) and EGFRvIII, erbB2 (HER2 or HER2/neu), erbB3 (HER3) and erbB4 (HER4).

69. The method of claim 66, wherein the cell-associated protein is selected from the group consisting of Tyrosinase, Melan-A/MART-1, tyrosinase related protein (TRP)-1/gp75, Polymorphic epithelial mucin (PEM), and Human epithelial mucin (MUC1).

70. The method of claim 66, wherein the secreted protein is selected from the group consisting of Monoclonal immunoglobulin, Immunoglobulin light chains, α-fetoprotein, Kallikreins 6 and 10, Gastrin-releasing peptide/bombesin, and Prostate specific antigen.

71. The method of claim 40, wherein the cancer antigen is a cancer testis (CT) antigen.

72. The method of claim 71, wherein the cancer testis (CT) antigen is selected from the group consisting of MAGE, MAGE-A1, -A3, -A6, -A12, MAGE-3, BAGE, GAGE, GAGE -1, -2, -3, -4, -5, -6, -7, and -8, HAGE, LAGE-1, NY-ESO-1, RAGE, RAGE-1, -2, -4, SSX, SSX-1, -2, -3, -4, -5, -6, -7, -8, -9, HOM-TES-14/SCP-1, HOM-TES-85, HOM-MEL-40, and PRAME.

73. The method of claim 40, wherein the cancer antigen is a non-tissue or non-lineage specific antigen.

74. The method of claim 73, wherein the non-tissue or non-lineage specific antigen is a carcinoembryonic antigen family member.

75. The method of claim 74, wherein the carcinoembryonic antigen family member is selected from the group consisting of CD66a, CD66b, CD66c, CD66d and CD66e.

76. The method of claim 40, wherein the cancer antigen is a viral protein.

77. The method of claim 76, wherein the viral protein is selected from the group consisting of Human papilloma virus protein, and EBV-encoded nuclear antigen (EBNA)-1.

78. The method of claim 40, wherein the cancer antigen is an antigen that is mutated or aberrantly expressed in a cancer.

79. The method of claim 78, wherein the antigen that is mutated or aberrantly expressed in a cancer is CDK4 or beta-catenin.

80. The method of claim 40, wherein the cancer antigen is selected from the group consisting of VEGF, Anti-idiotypic mAb (GD3 ganglioside mimic), CD20, CD52, Anti-idiotypic mAb (CEA mimic), ERBB2, EGFR, CD22, ERBB2 X CD65 (fcγRI), CD33, EpCam, and PEM.

81. A method of preventing an infectious disease in a subject at risk of developing an infectious disease comprising

identifying a subject at risk of developing an infectious disease, and

administering an agent of Formula I to the subject in an amount effective to induce IL-1.

82. The method of claim 81, further comprising administering to the subject a microbial antigen.

83. The method of claim 81, wherein the infectious disease is selected from the group consisting of a bacterial infection, a mycobacterial infection, a viral infection, a fungal infection and a parasitic infection.

84. The method of claim 83, wherein the bacterial infection is selected from the group consisting of an E. coli infection, a Staphylococcal infection, a Streptococcal infection, a Pseudomonas infection, Clostridium difficile infection, Legionella infection, Pneumococcus infection, Haemophilus infection, Klebsiella infection, Enterobacter infection, Citrobacter infection, Neisseria infection, Shigella infection, Salmonella infection, Listeria infection, Pasteurella infection, Streptobacillus infection, Spirillum infection, Treponema inection, Actinomyces infection, Borrelia infection, Corynebacterium infection, Nocardia infection, Gardnerella infection, Campylobacter infection, Spirochaeta infection, Proteus infection, Bacteriodes infection, H. pylori infection, and anthrax infection.

85. The method of claim 83, wherein the viral infection is selected from the group consisting of an HIV infection, a Herpes simplex virus 1 infection, a Herpes simplex virus 2 infection, cytomegalovirus infection, hepatitis A virus infection, hepatitis B virus infection, hepatitis C virus infection, human papilloma virus infection, Epstein Barr virus infection, rotavirus infection, adenovirus infection, influenza A virus infection, respiratory syncytial virus infection, varicella-zoster virus infections, small pox infection, monkey pox infection and SARS infection.

86. The method of claim 83, wherein the fungal infection is selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

87. The method of claim 83, wherein the parasite infection is selected from the group consisting of amebiasis, Trypanosoma cruzi infection, Fascioliasis, Leishmaniasis, Plasmodium infections, Onchocerciasis, Paragonimiasis, Trypanosoma brucei infection, Pneumocystis infection, Trichomonas vaginalis infection, Taenia infection, Hymenolepsis infection, Echinococcus infections, Schistosomiasis, neurocysticercosis, Necator americanus infection, and Trichuris trichuria infection.

88. The method of claim 83, wherein the viral infection is selected from the group consisting of a Herpes simplex virus 1 infection, a Herpes simplex virus 2 infection, cytomegalovirus infection, hepatitis A virus infection, hepatitis B virus infection, hepatitis C virus infection, human papilloma virus infection, Epstein Barr virus infection, rotavirus infection, adenovirus infection, influenza A virus infection, respiratory syncytial virus infection, varicella-zoster virus infections, small pox infection, monkey pox infection and SARS infection.

89. The method of claim 83, wherein the mycobacterial infection selected from the group consisting of leprosy and tuberculosis.

90. A method for stimulating an immune response in a non-immunocompromised subject comprising

administering to a subject in need thereof an agent of Formula I, in an amount effective to induce IL-1.

91. The method of claim 90, wherein the subject is a subject having or at risk of developing cancer.

92. The method of claim 90, further comprising administering to the subject an antibody or antibody fragment.

93. The method of claim 90, further comprising administering to the subject an antigen.

94. The method of claim 90, wherein the subject is elderly.

95. The method of claim 90, wherein the subject is at risk of developing influenza.

96. The method of claim 90, wherein the subject is at risk of angina.

97. A method for stimulating an immune response in an immunocompromised subject comprising

administering to a subject in need thereof an agent of Formula I, in an amount effective to induce IL-1.

98. The method of claim 97, wherein the immunocompromised subject is genetically immunocompromised.

99. The method of claim 98, wherein the subject has a genetic deficiency selected from the group consisting of SCID, agammaglobulinemia, and CDG.

100. The method of claim 97, wherein the subject has an immunoglobulin deficiency that is common variable immunodeficiency.

101. The method of claim 97, wherein the subject is a subject having or at risk of developing cancer.

102. The method of claim 97, further comprising administering to the subject an antibody or antibody fragment.

103. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is selected from the group consisting of trastuzumab, alemtuzumab (B cell chronic lymphocytic leukemia), gemtuzumab ozogamicin (CD33+ acute myeloid leukemia), hP67.6 (CD33+ acute myeloid leukemia), infliximab (inflammatory bowel disease and rheumatoid arthritis), etanercept (rheumatoid arthritis), rituximab, tositumomab, MDX-210, oregovomab, anti-EGF receptor mAb, MDX-447, anti-tissue factor protein (TF), (Sunol); ior-c5, c5, edrecolomab, ibritumomab tiuxetan, anti-idiotypic mAb mimic of ganglioside GD3 epitope, anti-HLA-Dr10 mAb, anti-CD33 humanized mAb, anti-CD52 humAb, anti-CD1 mAb (ior t6), MDX-22, celogovab, anti-17-1A mAb, bevacizumab, daclizumab, anti-TAG-72 (MDX-220), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-1), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-2), anti-CEA Ab, hmAbH11,

anti-DNA or DNA-associated proteins (histones) mAb, Gliomab-H mAb, GNI-250 mAb, anti-CD22, CMA 676), anti-idiotypic human mAb to GD2 ganglioside, ior egf/r3, anti-ior c2 glycoprotein mAb, ior c5, anti-FLK-2/FLT-3 mAb, anti-GD-2 bispecific mAb, antinuclear autoantibodies, anti-HLA-DR Ab, anti-CEA mAb, palivizumab, bevacizumab, alemtuzumab, BLyS-mAb, anti-VEGF2, anti-Trail receptor; B3 mAb, mAb BR96, breast cancer; and Abx-Cbl mAb.

104. The method of claim 97, further comprising administering to the subject an antigen.

105. The method of claim 93 or 104, wherein the antigen is a cancer antigen or a microbial antigen.

106. The method of claim 24, 82 or 105, wherein the microbial antigen is selected from the group consisting of a bacterial antigen, a mycobacterial antigen, a viral antigen, a fungal antigen, and a parasitic antigen.

107. The method of claim 106, wherein the bacterial antigen is derived from a bacterial species selected from the group consisting of E. coli, Staphylococcal, Streptococcal, Pseudomonas, Clostridium difficile, Legionella, Pneumococcus, Haemophilus, Klebsiella, Enterobacter, Citrobacter, Neisseria, Shigella, Salmonella, Listeria, Pasteurella, Streptobacillus, Spirillum, Treponema, Actinomyces, Borrelia, Corynebacterium, Nocardia, Gardnerella, Campylobacter, Spirochaeta, Proteus, Bacteriodes, H. pylori, and anthrax.

108. The method of claim 106, wherein the viral antigen is derived from a viral species selected from the group consisting of HIV, Herpes simplex virus 1, Herpes simplex virus 2, cytomegalovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, human papilloma virus, Epstein Barr virus, rotavirus, adenovirus, influenza A virus, respiratory syncytial virus, varicella-zoster virus, small pox, monkey pox infection and SARS infection.

109. The method of claim 106, wherein the fungal antigen is derived from a fungal species that causes an infection selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

110. The method of claim 106, wherein the parasitic antigen is derived from a parasite species selected from the group consisting of amebiasis, Trypanosoma cruzi, Fascioliasis, Leishmaniasis, Plasmodium, Onchocerciasis, Paragonimiasis, Trypanosoma brucei, Pneumocystis, Trichomonas

vaginalis, Taenia, Hymenolepsis, Echinococcus, Schistosomiasis, neurocysticercosis, Necator americanus, and Trichuris trichuria.

111. The method of claim 106, wherein the mycobacterial antigen is derived from a mycobacterial species selected from the group consisting of M. tuberculosis and M. leprae.

112. The method of claim 105, wherein the cancer antigen is selected from the group consisting of MART-1/Melan-A, gp100, adenosine deaminase-binding protein (ADAbp), FAP, cyclophilin b, colorectal associated antigen (CRC)--C017-1A/GA733, carcinoembryonic antigen (CEA), CAP-1, CAP-2, etv6, AML1, prostate specific antigen (PSA), PSA-1, PSA-2, PSA-3, prostate-specific membrane antigen (PSMA), T-cell receptor/CD3-zeta chain, HER 2, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, VEGFR and CD20.

113. The method of claim 105, wherein the cancer antigen is selected from the group consisting of MAGE-A1, MAGE-A2, MAGE-A3, MAGE-A4, MAGE-A5, MAGE-A6, MAGE-A7, MAGE-A8, MAGE-A9, MAGE-A10, MAGE-A11, MAGE-A12, MAGE-Xp2 (MAGE-B2), MAGE-Xp3 (MAGE-B3), MAGE-Xp4 (MAGE-B4), MAGE-C1, MAGE-C2, MAGE-C3, MAGE-C4, MAGE-C5).

114. The method of claim 105, wherein the cancer antigen is selected from the group consisting of GAGE-1, GAGE-2, GAGE-3, GAGE-4, GAGE-5, GAGE-6, GAGE-7, GAGE-8, GAGE-9.

115. The method of claim 105, wherein the cancer antigen is selected from the group consisting of BAGE, RAGE, LAGE-1, NAG, GnT-V, MUM-1, CDK4, tyrosinase, p53, MUC family, HER2/neu, p21ras, RCAS1, α-fetoprotein, E-cadherin, α-catenin, β-catenin, γ-catenin, p120ctn, $gp100^{Pmel117}$, PRAME, NY-ESO-1, cdc27, adenomatous polyposis coli protein (APC), fodrin, Connexin 37, Ig-idiotype, p15, gp75, GM2 ganglioside, GD2 ganglioside, human papilloma virus proteins, Smad family of tumor antigens, Imp-1, P1A, EBV-encoded nuclear antigen (EBNA)-1, brain glycogen phosphorylase, SSX-1, SSX-2 (HOM-MEL-40), SSX-1, SSX-4, SSX-5, SCP-1 and CT-7, and c-erbB-2.

116. The method of claim 90 or 97, wherein the subject will have a surgery.

117. The method of claim 90 or 97, wherein the subject has a skin abrasion from a trauma.

118. The method of claim 90 or 97, wherein the subject is traveling to a region in which a microbial infection is common.

119. The method of claim 93 or 104, wherein the agent of Formula I and the antigen are formulated together.

120. The method of claim 93 or 104, wherein the antigen is administered mucosally.

121. The method of claim 90 or 97, wherein the agent of Formula I is administered orally.

122. The method of claim 90 or 97, wherein the agent of Formula I is administered mucosally.

123. The method of claim 97, wherein the subject has been treated with an agent selected from the group consisting of a cox-1 inhibitor, a cox-2 inhibitor, and a steroid.

124. The method of claim 123, wherein the agent is celecoxib, rofecoxib, naproxen or aspirin.

125. The method of claim 97, wherein the subject is a substance abuse subject.

126. The method of claim 126, wherein the substance is selected from the group consisting of alcohol and intravenous drug.

127. The method of claim 97, wherein the subject has gingivitis, osteomyelitis, diabetes type I, diabetes type II, chronic granuloma, chronic hepatitis, and chronic EBV infection.

128. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cell surface molecule.

129. The method of claim 128, wherein the cell surface molecule is selected from the group consisting of HER 2, CD20, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, VEGFR.

130. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cancer antigen.

131. The method of claim 130, wherein the cancer antigen is selected from the group consisting of HER 2 (p185), CD20, CD33, GD3 ganglioside, GD2 ganglioside, carcinoembryonic antigen (CEA), CD22, milk mucin core protein, TAG-72, Lewis A antigen, ovarian associated antigens such as OV-TL3 and MOv18, high Mr melanoma antigens recognized by antibody 9.2.27, HMFG-2, SM-3, B72.3, PR5C5, and PR4D2.

132. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a stromal cell molecule.

133. The method of claim 132, wherein the stromal cell molecule is selected from the group consisting of FAP and CD26.

134. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for an extracellular matrix molecule.

135. The method of claim 132, wherein the extracellular matrix molecule is selected from the group consisting of collagen, glycosaminoglycans (GAGs), proteoglycans, elastin, fibronectin and laminin.

136. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a tumor vasculature associated antigen.

137. The method of claim 136, wherein the tumor vasculature associated antigen is selected from the group consisting of endoglin, ELAM-1, VCAM-1, ICAM-1, ligand reactive with LAM-1, MHC class II antigens, aminophospholipids such as phosphatidylserine and phosphatidylethanolamine, VEGFR1 (Flt-1), VEGFR2 (KDR/Flk-1), and a complex of a growth factor and its receptor such as a complex of FGF and the FGFR or a complex of TGFβ and the TGFβR.

138. The method of claim 136, wherein the antibody or antibody specific for a tumor vasculature associated antigen is selected from the group consisting of TEC-4 and TEC-11, 2C3 (ATCC PTA 1595), GV39 and GV97.

139. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is administered on a first day of a seven day cycle and the agent of Formula I is administered twice a day on day two through day seven.

140. The method of claim 139, wherein the seven day cycle is repeated twice, thrice, or four times.

141. The method of claim 139, wherein the seven day cycle is repeated for a month, two months, or three months.

142. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is conjugated to a toxin derived from plant, fungus, or bacteria.

143. The method of claim 142, wherein the toxin is selected from the group consisting of A chain toxin, deglycosylated A chain toxin, ribosome inactivating protein, α-sarcin, aspergillin, restrictocin, ribonuclease, diptheria toxin and Pseudomonas exotoxin.

144. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is conjugated to a chemotherapeutic agent or a radioisotope.

145. The method of claim 144, wherein the chemotherapeutic agent is selected from the group consisting of an anti-metabolite, an anthracycline, a vinca alkaloid, an antibiotic, an alkylating agent, and an epipodophyllotoxin.

146. The method of claim 105 or 130, wherein the cancer antigen is a gene or gene product thereof that has undergone chromosomal alteration.

147. The method of claim 146, wherein the gene product is a RNA or protein gene product.

148. The method of claim 146, wherein the gene or gene product that has undergone chromosomal alteration is selected from the group consisting of gene or gene products associated with activation of quiescent genes, and gene or gene products associated with a novel fusion gene and protein.

149. The method of claim 148, wherein the gene or gene products associated with activation of quiescent genes is selected from the group consisting of *BCL-1 and IgH, BCL-2 and IgH, BCL-6, TAL-1 and TCRδ or SIL, c-MYC and IgH or IgL, MUN/IRF4 and IgH*, and *PAX-5 (BSAP).*

150. The method of claim 148, wherein the gene or gene products associated with a novel fusion gene and protein is selected from the group consisting of *RARα, PML, PLZF, NPM or NuMA; BCR and ABL; MLL (HRX); E2A and PBX or HLF; NPM, ALK*; and *NPM, MLF-1.*

151. The method of claim 105 or 130, wherein the cancer antigen is a tissue- or lineage-specific antigen.

152. The method of claim 151, wherein the tissue- or lineage-specific antigen is a cell surface protein, epidermal growth factor receptor, cell-associated protein, or a secreted protein.

153. The method of claim 152, wherein the cell surface protein is selected from the group consisting of CD20, CD22, CD52, CD33, CD10 (gp100), CD3/T-cell receptor (TCR), CD79/B-cell receptor (BCR), CD26, Human leukocyte antigen (HLA)-DR, HLA-DP, and HLA-DQ, RCAS1, and Prostate specific membrane antigen.

154. The method of claim 152, wherein the epidermal growth factor receptor is selected from the group consisting of EGFR (HER1 or erbB1) and EGFRvIII, erbB2 (HER2 or HER2/neu), erbB3 (HER3), and erbB4 (HER4).

155. The method of claim 152, wherein the cell-associated protein is selected from the group consisting of Tyrosinase, Melan-A/MART-1, tyrosinase related protein (TRP)-1/gp75, Polymorphic epithelial mucin (PEM), and Human epithelial mucin (MUC1).

156. The method of claim 152, wherein the secreted protein is selected from the group consisting of Monoclonal immunoglobulin, Immunoglobulin light chains, α-fetoprotein, Kallikreins 6 and 10, Gastrin-releasing peptide/bombesin, and Prostate specific antigen.

157. The method of claim 105 or 130, wherein the cancer antigen is a cancer testis (CT) antigen.

158. The method of claim 157, wherein the cancer testis (CT) antigen is selected from the group consisting of MAGE, MAGE-A1, -A3, -A6, -A12, MAGE-3, BAGE, GAGE, GAGE -1, -2, -3, -4, -5, -6, -7, and -8, HAGE, LAGE-1, NY-ESO-1, RAGE, RAGE-1, -2, -4, SSX, SSX-1, -2, -3, -4, -5, -6, -7, -8, -9, HOM-TES-14/SCP-1, HOM-TES-85, HOM-MEL-40, and PRAME.

159. The method of claim 105 or 130, wherein the cancer antigen is a non-tissue or non-lineage specific antigen.

160. The method of claim 159, wherein the non-tissue or non-lineage specific antigen is a carcinoembryonic antigen family member.

161. The method of claim 160, wherein the carcinoembryonic antigen family member is selected from the group consisting of CD66a, CD66b, CD66c, CD66d and CD66e.

162. The method of claim 105 or 130, wherein the cancer antigen is a viral protein.

163. The method of claim 162, wherein the viral protein is selected from the group consisting of Human papilloma virus protein, and EBV-encoded nuclear antigen (EBNA)-1.

164. The method of claim 105 or 130, wherein the cancer antigen is an antigen that is mutated or aberrantly expressed in a cancer.

165. The method of claim 164, wherein the antigen that is mutated or aberrantly expressed in a cancer is CDK4 or beta-catenin.

166. The method of claim 1, 92 or 102, wherein the antibody or antibody fragment is selected from the group consisting of Avastin (bevacizumab), BEC2 (mitumomab), Bexxar (tositumomab), Campath (alemtuzumab), CeaVac, Herceptin (trastuzumab), IMC-C225 (centuximab), LymphoCide (epratuzumab), MDX-210, Mylotarg (gemtuzumab ozogamicin), Panorex (edrecolomab), Rituxan (rituximab), Theragyn (pemtumomab), Zamyl, and Zevalin (ibritumomab tituxetan).

167. The method of claim 105 or 130, wherein the cancer antigen is selected from the group consisting of VEGF, Anti-idiotypic mAb (GD3 ganglioside mimic), CD20, CD52, Anti-idiotypic mAb (CEA mimic), ERBB2, EGFR, CD22, ERBB2 X CD65 (fcγRI), CD33, EpCam, and PEM.

168. A method for treating a subject having or at risk of developing an IFN-responsive condition comprising

administering to a subject in need of such treatment an agent of Formula I in an amount effective to induce a therapeutically or prophylactically effective amount of IL-1 in the subject.

169. The method of claim 168, wherein the IFN-responsive condition is a chronic infection selected from the group consisting of a chronic hepatitis B infection, chronic hepatitis C infection, chronic Epstein Barr Virus infection, and tuberculosis.

170. The method of claim 169, further comprising administering a second active agent selected from the group consisting of IFNα, pegylated IFN, IFNα-2b, acyclovir, lobucavir, ganciclovir, L-deoxythymidine, clevudine, a therapeutic vaccine, phosphonoformate (PFA), ribavirin (RBV), thymosin alpha-1, 2 3-dideoxy-3-fluoroguanosine (FLG), famciclovir, lamivudine, adefovir dipivoxil, entecavir, emtricitabine, and hepatitis B-specific immunoglobulin.

171. The method of claim 169, wherein the subject is HIV positive.

172. The method of claim 168, wherein the disorder has become drug resistant.

173. The method of claim 168, wherein the disorder is multiple sclerosis.

174. The method of claim 168, wherein IFN is selected from the group consisting of IFNα, IFNα-2b, IFNβ, IFN-γ.

175. The method of claim 168, wherein the IFN-responsive condition is an IFN-γ responsive condition.

176. The method of claim 175, wherein the IFN-γ responsive condition is selected from the group consisting of viral infections and associated diseases, and cancer.

177. A method for treating a subject having or at risk of developing cancer comprising administering to a subject in need of such treatment an enzyme inhibitor selected from the group consisting of a tyrosine kinase inhibitor, a CDK inhibitor, a MAP kinase inhibitor, and an EGFR inhibitor, and an agent of Formula I in an amount effective to inhibit the cancer.

178. The method of claim 177, wherein the amount effective is a synergistic amount.

179. The method of claim 177, wherein the CDK inhibitor is selected from the group consisting of p21, p27, p57, p15, p16, p18, and p19.

180. The method of claim 177, wherein the MAP kinase inhibitor is selected from the group consisting of KY12420 ($C_{23}H_{24}O_8$), CNI-1493, PD98059, 4-(4-Fluorophenyl)-2-(4-methylsulfinyl phenyl)-5-(4-pyridyl) 1H-imidazole.

181. The method of claim 177, wherein the EGFR inhibitor is selected from the group consisting of Tarceva™(OSI-774), Iressa (ZD1839), WHI-P97 (quinazoline derivative), LFM-A12 (leflunomide metabolite analog), AG1458.

182. A method for treating a subject having or at risk of developing cardiovascular disease comprising

administering to a subject in need of such treatment an agent of Formula I in an amount effective to induce an effective amount of IL-1.

183. The method of claim 182, further comprising identifying the subject in need of such treatment.

184. A method for preventing drug resistance in a subject having an infectious disease comprising

administering to a subject receiving an anti-microbial agent, an agent of Formula I in an amount effective to reduce the risk of resistance to the anti-microbial agent.

185. The method of claim 184, wherein the infectious disease is selected from the group consisting of a bacterial infection, a mycobacterial infection, a viral infection, a fungal infection and a parasitic infection.

186. The method of claim 184, wherein the bacterial infection is a Pseudomonas infection.

187. The method of claim 184, wherein the anti-microbial agent is selected from the group consisting of an anti-bacterial agent, an anti-mycobacterial agent, an anti-viral agent, an anti-fungal agent, and an anti-parasitic agent.

188. A method of shortening a vaccination course comprising

administering to a subject in need of immunization an agent of Formula I in an amount effective to induce an antigen-specific immune response to a vaccine administered in a vaccination course,

wherein the vaccination course is shortened by at least one immunization.

189. The method of claim 188, wherein the vaccine is for hepatitis virus.

190. The method of claim 189, wherein hepatitis is hepatitis B virus.

191. A method of shortening a vaccination course comprising

administering to a subject in need of immunization an agent of Formula I in an amount effective to induce an antigen-specific immune response to a vaccine administered in a vaccination course,

wherein the vaccination course is shortened by at least one day.

192. The method of claim 188 or 191, wherein the agent of Formula I is administered substantially simultaneously with the vaccine.

193. The method of claim 191, wherein the vaccine is for hepatitis virus.

194. The method of claim 193, wherein hepatitis virus is hepatitis B virus.

195. A method for stimulating an immune response in a subject having cancer comprising

administering to a subject in need of such treatment an agent of Formula I in an amount effective to stimulate an antigen-specific immune response, prior to and following a therapy selected from the group consisting of radiation, surgery and chemotherapy.

196. The method of claim 195, wherein the agent of Formula I is administered to the subject 30 minutes to 8 hours before the therapy and 30 minutes to 8 hours after the therapy.

197. A method for stimulating an immune response in a subject at risk of developing cancer comprising

administering to a subject in need of such treatment an agent of Formula I in an amount effective to stimulate an antigen-specific immune response.

198 The method of claim 197, further comprising identifying a subject in need of such treatment.

199. The method of claim 197, wherein the subject at risk of developing cancer has a familial predisposition to developing cancer.

200. The method of claim 199, wherein the familial predisposition is familial colon polyposis.

201. The method of claim 197, wherein the subject has precancerous polyps.

202. The method of claim 197, wherein the subject has precancerous HPV lesions.

203. The method of claim 195 or 197, wherein the cancer is selected from the group consisting of a lymphoma or leukemia.

204. The method of claim 195 or 197, wherein the cancer is selected from the group consisting of basal cell carcinoma, biliary tract cancer; bladder cancer; bone cancer; brain cancer; breast cancer; cervical cancer; choriocarcinoma; CNS cancer; colon and rectum cancer; connective tissue cancer; cancer of the digestive system; endometrial cancer; esophageal cancer; eye cancer; cancer of the head and neck; gastric cancer; intra-epithelial neoplasm; kidney cancer; larynx cancer; leukemia; acute myeloid leukemia, acute lymphoid leukemia, chronic myeloid leukemia, chronic lymphoid leukemia, liver cancer; small cell lung cancer; non-small cell lung cancer; lymphoma, Hodgkin's lymphoma; Non-Hodgkin's lymphoma; melanoma; myeloma; neuroblastoma; oral cavity cancer; ovarian cancer; pancreatic cancer; prostate cancer; retinoblastoma; rhabdomyosarcoma; rectal cancer; renal cancer; cancer of the respiratory system; sarcoma; skin cancer; stomach cancer; testicular cancer; thyroid cancer; uterine cancer; and cancer of the urinary system.

205. The method of claim 195 or 197, wherein the cancer is selected from the group consisting of bladder cancer, breast cancer, colon cancer, endometrial cancer, head and neck cancer, leukemia, lung cancer, lymphoma, melanoma, ovarian cancer, prostate cancer and rectal cancer.

206. The method of claim 195 or 197, wherein the cancer is a metastasis.

207. The method of claim 195 or 197, further comprising administering an adjuvant to the subject.

208. The method of claim 207, wherein the adjuvant is selected from the group consisting of alum, cholera toxin, CpG immunostimulatory nucleic acids, MPL, MPD, and QS-21.

209. The method of claim 195 or 197, wherein the agent of Formula I is administered in a dose of greater than 10^{-8}M.

210. A method for modulating an immune response comprising

administering to a subject in need thereof an antibody or an antibody fragment on a first day of a seven day cycle, and administering to the subject an agent of Formula I on day 2 through to day 7 of the seven day cycle.

211. The method of claim 210, wherein the agent is administered twice a day on day 2 through to day 7.

212. The method of claim 210, wherein the seven day cycle is repeated twice, thrice, or four times.

213. The method of claim 210, wherein the seven day cycle is repeated for a month or two months.

214. The method of claim 210, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cell surface molecule.

215. The method of claim 214, wherein the cell surface molecule is selected from the group consisting of HER 2, CD20, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, VEGFR.

216. The method of claim 210, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cancer antigen.

217. The method of claim 216, wherein the cancer antigen is selected from the group consisting of HER 2 (p185), CD20, CD33, GD3 ganglioside, GD2 ganglioside, carcinoembryonic antigen (CEA), CD22, milk mucin core protein, TAG-72, Lewis A antigen, ovarian associated antigens such as OV-TL3 and MOv18, high Mr melanoma antigens recognized by antibody 9.2.27, HMFG-2, SM-3, B72.3, PR5C5, PR4D2.

218. The method of claim 210, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a stromal cell molecule.

219. The method of claim 218, wherein the stromal cell molecule is selected from the group consisting of FAP and CD26.

220. The method of claim 210, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for an extracellular matrix molecule.

221. The method of claim 220, wherein the extracellular matrix molecule is selected from the group consisting of collagen, glycosaminoglycans (GAGs), proteoglycans, elastin, fibronectin and laminin.

222. The method of claim 210, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a tumor vasculature associated antigen.

223. The method of claim 222, wherein the tumor vasculature associated antigen is selected from the group consisting of endoglin, ELAM-1, VCAM-1, ICAM-1, ligand reactive with LAM-1, MHC class II antigens, aminophospholipids such as phosphatidylserine and phosphatidylethanolamine, VEGFR1 (Flt-1), VEGFR2 (KDR/Flk-1), a complex of a growth factor and its receptor such as a complex of FGF and the FGFR or a complex of TGFβ and the TGFβR.

224. The method of claim 222, wherein the antibody or antibody specific for a tumor vasculature associated antigen is selected from the group consisting of TEC-4 and TEC-11, 2C3 (ATCC PTA 1595), GV39 and GV97.

225. The method of claim 210, wherein the antibody or antibody fragment is conjugated to a toxin derived from plant, fungus, or bacteria.

226. The method of claim 225, wherein the toxin is selected from the group consisting of A chain toxin, deglycosylated A chain toxin, ribosome inactivating protein, α-sarcin, aspergillin, restrictocin, ribonuclease, diptheria toxin and Pseudomonas exotoxin.

227. The method of claim 210, wherein the antibody or antibody fragment is conjugated to a chemotherapeutic agent, a radioisotope or a cytotoxin.

228. The method of claim 227, wherein the chemotherapeutic agent is selected from the group consisting of an anti-metabolite, an anthracycline, a vinca alkaloid, an antibiotic, an alkylating agent, and an epipodophyllotoxin.

229. The method of claim 216, wherein the cancer antigen is a gene or gene product thereof that has undergone chromosomal alteration.

230. The method of claim 229, wherein the gene product is a RNA or protein gene product.

231. The method of claim 229, wherein the gene or gene product that has undergone chromosomal alteration is selected from the group consisting of gene or gene products associated with activation of quiescent genes, and gene or gene products associated with a novel fusion gene and protein.

232. The method of claim 231, wherein the gene or gene products associated with activation of quiescent genes is selected from the group consisting of *BCL-1 and IgH, BCL-2 and IgH, BCL-6, TAL-1 and TCRδ or SIL, c-MYC and IgH or IgL, MUN/IRF4 and IgH,* and *PAX-5 (BSAP).*

233. The method of claim 231, wherein the gene or gene products associated with a novel fusion gene and protein is selected from the group consisting of *RARα, PML, PLZF, NPM or NuMA, BCR and ABL, MLL (HRX), E2A and PBX or HLF, NPM, ALK,* and *NPM, MLF-1.*

234. The method of claim 216, wherein the cancer antigen is a tissue- or lineage-specific antigen.

235. The method of claim 234, wherein the tissue- or lineage-specific antigen is a cell surface protein, epidermal growth factor receptor, cell-associated protein, or a secreted protein.

236. The method of claim 235, wherein the cell surface protein is selected from the group consisting of CD20, CD22, CD52, CD33, CD10 (gp100), CD3/T-cell receptor (TCR), CD79/B-cell receptor (BCR), CD26, Human leukocyte antigen (HLA)-DR, HLA-DP, and HLA-DQ, RCAS1, and Prostate specific membrane antigen.

237. The method of claim 235, wherein the epidermal growth factor receptor is selected from the group consisting of EGFR (HER1 or erbB1) and EGFRvIII, erbB2 (HER2 or HER2/neu), erbB3 (HER3), and erbB4 (HER4).

238. The method of claim 235, wherein the cell-associated protein is selected from the group consisting of Tyrosinase, Melan-A/MART-1, tyrosinase related protein (TRP)-1/gp75, Polymorphic epithelial mucin (PEM), and Human epithelial mucin (MUC1).

239. The method of claim 235, wherein the secreted protein is selected from the group consisting of Monoclonal immunoglobulin, Immunoglobulin light chains, α-fetoprotein, Kallikreins 6 and 10, Gastrin-releasing peptide/bombesin, and Prostate specific antigen.

240. The method of claim 216, wherein the cancer antigen is a cancer testis (CT) antigen.

241. The method of claim 240, wherein the cancer testis (CT) antigen is selected from the group consisting of MAGE, MAGE-A1, -A3, -A6, -A12, MAGE-3, BAGE, GAGE, GAGE -1, -2, -3, -4, -5, -6, -7, and -8, HAGE, LAGE-1, NY-ESO-1, RAGE, RAGE-1, -2, -4, SSX, SSX-1, -2, -3, -4, -5, -6, -7, -8, -9, HOM-TES-14/SCP-1, HOM-TES-85, HOM-MEL-40, and PRAME.

242. The method of claim 216, wherein the cancer antigen is a non-tissue or non-lineage specific antigen.

243. The method of claim 242, wherein the non-tissue or non-lineage specific antigen is a carcinoembryonic antigen family member.

244. The method of claim 243, wherein the carcinoembryonic antigen family member is selected from the group consisting of CD66a, CD66b, CD66c, CD66d and CD66e.

245. The method of claim 216, wherein the cancer antigen is a viral protein.

246. The method of claim 245, wherein the viral protein is selected from the group consisting of Human papilloma virus protein and EBV-encoded nuclear antigen (EBNA)-1.

247. The method of claim 216, wherein the cancer antigen is an antigen that is mutated or aberrantly expressed in a cancer.

248. The method of claim 247, wherein the antigen that is mutated or aberrantly expressed in a cancer is CDK4 or beta-catenin.

249. The method of claim 210, wherein the antibody or antibody fragment is selected from the group consisting of Avastin (bevacizumab), BEC2 (mitumomab), Bexxar (tositumomab), Campath (alemtuzumab), CeaVac, Herceptin (trastuzumab), IMC-C225 (centuximab), LymphoCide

(epratuzumab), MDX-210, Mylotarg (gemtuzumab ozogamicin), Panorex (edrecolomab), Rituxan (rituximab), Theragyn (pemtumomab), Zamyl, and Zevalin (ibritumomab tituxetan).

250. The method of claim 216, wherein the cancer antigen is selected from the group consisting of VEGF, Anti-idiotypic mAb (GD3 ganglioside mimic), CD20, CD52, Anti-idiotypic mAb (CEA mimic), ERBB2, EGFR, CD22, ERBB2 X CD65 (fcγRI), CD33, EpCam, and PEM.

251. The method of claim 1, 18, 24, 81, 90, 97, 168, 177, 182, 184, 188, 191, 195, 197 or 210 wherein the agent of Formula I is an agent of Formula II.

252. The method of claim 1, 18, 24, 81, 90, 97, 168, 177, 182, 184, 188, 191, 195, 197 or 210 wherein the agent of Formula I is an agent of Formula III.

253. The method of claim 1, 18, 24, 81, 90, 97, 168, 177, 182, 184, 188, 191, 195, 197 or 210 wherein the agent of Formula I is selected from the group consisting of L-Val-L-boroPro, L-Met-L-boroPro, and L-Ile-L-boroPro.

254. The method of claim 1, 18, 24, 81, 90, 97, 168, 177, 182, 184, 191, 195, 197 or 210, wherein the agent of Formula I is in a cyclic form.

255. The method of claim 1, 18, 24, 177, 182, 188, 191, 195, 197 or 210, wherein the agent of Formula I is administered in an amount that increases lymphoid tissue levels of IL-1, G-CSF or IL-8.

256. The method of claim 1, 18, 24, 177, 182, 184, 188, 191, 195, 197 or 210, wherein the agent of Formula I is administered in an amount that does not increase serum IL-1 levels.

257. The method of claim 1, 18, 24, 81, 90, 97, 168, 177, 182, 184, 188, 191, 195, 197 or 210, wherein the IL-1 is IL-1α or IL-1β.

258. The method of claim 1,18, 24, 81, 90, 97, 168, 177, 182, 184, 188, 191, 195, 197 or 210, wherein the subject is otherwise free of symptoms calling for hematopoietic stimulation.

259. The method of claim 1, 18, 24, 81, 90, 97, 168, 177, 182, 184, 188, 191, 195, 197 or 210, wherein the agent of Formula I is administered on a routine schedule.

260. The method of claim 1, 18, 24, 81, 90, 97, 168, 177, 182, 184, 188, 191, 195, 197 or 210, wherein the subject is HIV negative.

261. A composition comprising
an effective amount of an agent of Formula I and an antibody or antibody fragment.

262. The composition of claim 261, further comprising a pharmaceutically acceptable carrier.

263. The composition of claim 261, wherein the effective amount is an amount to stimulate antibody dependent cell-mediated cytoxicity.

264. The composition of claim 261, wherein the effective amount is an amount to treat or prevent an infectious disease.

265. The composition of claim 261, wherein the antibody or antibody fragment is an antibody.

266. The composition of claim 261, wherein the antibody or antibody fragment is selected from the group consisting of trastuzumab, alemtuzumab (B cell chronic lymphocytic leukemia), gemtuzumab ozogamicin (CD33+ acute myeloid leukemia), hP67.6 (CD33+ acute myeloid leukemia), infliximab (inflammatory bowel disease and rheumatoid arthritis), etanercept (rheumatoid arthritis), rituximab, tositumomab, MDX-210, oregovomab, anti-EGF receptor mAb, MDX-447, anti-tissue factor protein (TF), (Sunol); ior-c5, c5, edrecolomab, ibritumomab tiuxetan, anti-idiotypic mAb mimic of ganglioside GD3 epitope, anti-HLA-Dr10 mAb, anti-CD33 humanized mAb, anti-CD52 humAb, anti-CD1 mAb (ior t6), MDX-22, celogovab, anti-17-1A mAb, bevacizumab, daclizumab, anti-TAG-72 (MDX-220), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-1), anti-idiotypic mAb mimic of high molecular weight proteoglycan (I-Mel-2), anti-CEA Ab, hmAbH11, anti-DNA or DNA-associated proteins (histones) mAb, Gliomab-H mAb, GNI-250 mAb, anti-CD22, CMA 676), anti-idiotypic human mAb to GD2 ganglioside, ior egf/r3, anti-ior c2 glycoprotein mAb, ior c5, anti-FLK-2/FLT-3 mAb, anti-GD-2 bispecific mAb, antinuclear autoantibodies, anti-HLA-DR Ab, anti-CEA mAb, palivizumab, bevacizumab, alemtuzumab, BLyS-mAb, anti-VEGF2, anti-Trail receptor; B3 mAb, mAb BR96, breast cancer; and Abx-Cbl mAb.

267. The composition of claim 261, wherein the antibody or antibody fragment is an anti-HER2 antibody.

268. The composition of claim 267, wherein the anti-HER2 antibody is trastuzumab.

269. The composition of claim 261, wherein the antibody or antibody fragment is an anti-CD20 antibody.

270. The composition of claim 269, wherein the anti-CD20 antibody is rituximab.

271. The composition of claim 261, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cell surface molecule.

272. The composition of claim 271, wherein the cell surface molecule is selected from the group consisting of HER 2, CD20, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, and VEGFR.

273. The composition of claim 261, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a cancer antigen.

274. The composition of claim 273, wherein the cancer antigen is selected from the group consisting of HER 2 (p185), CD20, CD33, GD3 ganglioside, GD2 ganglioside, carcinoembryonic antigen (CEA), CD22, milk mucin core protein, TAG-72, Lewis A antigen, ovarian associated antigens such as OV-TL3 and MOv18, high Mr melanoma antigens recognized by antibody 9.2.27, HMFG-2, SM-3, B72.3, PR5C5, and PR4D2.

275. The composition of claim 261, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a stromal cell molecule.

276. The composition of claim 275, wherein the stromal cell molecule is selected from the group consisting of FAP and CD26.

277. The composition of claim 261, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for an extracellular matrix molecule.

278. The composition of claim 277, wherein the extracellular matrix molecule is selected from the group consisting of collagen, glycosaminoglycans (GAGs), proteoglycans, elastin, fibronectin and laminin.

279. The composition of claim 261, wherein the antibody or antibody fragment is an antibody or antibody fragment specific for a tumor vasculature associated antigen.

280. The composition of claim 279, wherein the tumor vasculature associated antigen is selected from the group consisting of endoglin, ELAM-1, VCAM-1, ICAM-1, ligand reactive with LAM-1, MHC class II antigens, aminophospholipids such as phosphatidylserine and phosphatidylethanolamine, VEGFR1 (Flt-1), VEGFR2 (KDR/Flk-1), and a complex of a growth factor and its receptor such as a complex of FGF and the FGFR or a complex of TGFβ and the TGFβR.

281. The composition of claim 279, wherein the antibody or antibody specific for a tumor vasculature associated antigen is selected from the group consisting of TEC-4 and TEC-11, 2C3 (ATCC PTA 1595), GV39 and GV97.

282. The composition of claim 261, further comprising a housing and instructions for use.

283. The composition of claim 282, wherein the instructions for use indicate that the antibody or antibody fragment is administered on a first day of a seven day cycle and the agent of Formula I is administered twice a day on day two through day seven.

284. The composition of claim 283, wherein the seven day cycle is repeated twice, thrice, or four times.

285. The composition of claim 283, wherein the seven day cycle is repeated for a month, two months, or three months.

286. The composition of claim 261, wherein the antibody or antibody fragment is conjugated to a toxin derived from plant, fungus, or bacteria.

287. The composition of claim 286, wherein the toxin is selected from the group consisting of A chain toxin, deglycosylated A chain toxin, ribosome inactivating protein, α-sarcin, aspergillin, restrictocin, ribonuclease, diptheria toxin and Pseudomonas exotoxin.

288. The composition of claim 261, wherein the antibody or antibody fragment is conjugated to a chemotherapeutic agent or a radioisotope.

289. The composition of claim 288, wherein the chemotherapeutic agent is selected from the group consisting of an anti-metabolite, an anthracycline, a vinca alkaloid, an antibiotic, an alkylating agent, and an epipodophyllotoxin.

290. A composition comprising
an effective amount of an agent of Formula I and a cancer antigen.

291. The composition of claim 261 or 290, wherein the effective amount is an amount to treat or prevent cancer.

292. The composition of claim 290, wherein the cancer antigen is a peptide antigen.

293. The composition of claim 290, wherein the cancer antigen is a lipid antigen.

294. The composition of claim 290, wherein the cancer antigen is selected from the group consisting of MART-1/Melan-A, gp100, adenosine deaminase-binding protein (ADAbp), FAP, cyclophilin b, colorectal associated antigen (CRC)--C017-1A/GA733, carcinoembryonic antigen (CEA), CAP-1, CAP-2, etv6, AML1, prostate specific antigen (PSA), PSA-1, PSA-2, PSA-3, prostate-specific membrane antigen (PSMA), T-cell receptor/CD3-zeta chain, HER 2, CD33, EGF receptor, HLA markers such as HLA-DR, CD52, CD1, CEA, CD22, GD2 ganglioside, FLK2/FLT3, VEGF, VEGFR and CD20.

295. The composition of claim 290, wherein the cancer antigen is selected from the group consisting of MAGE-A1, MAGE-A2, MAGE-A3, MAGE-A4, MAGE-A5, MAGE-A6, MAGE-A7, MAGE-A8, MAGE-A9, MAGE-A10, MAGE-A11, MAGE-A12, MAGE-Xp2 (MAGE-B2), MAGE-Xp3 (MAGE-B3), MAGE-Xp4 (MAGE-B4), MAGE-C1, MAGE-C2, MAGE-C3, MAGE-C4, MAGE-C5).

296. The composition of claim 290, wherein the cancer antigen is selected from the group consisting of GAGE-1, GAGE-2, GAGE-3, GAGE-4, GAGE-5, GAGE-6, GAGE-7, GAGE-8, GAGE-9.

297. The composition of claim 290, wherein the cancer antigen is selected from the group consisting of BAGE, RAGE, LAGE-1, NAG, GnT-V, MUM-1, CDK4, tyrosinase, p53, MUC family,

HER2/neu, p21ras, RCAS1, α-fetoprotein, E-cadherin, α-catenin, β-catenin, γ-catenin, p120ctn, $gp100^{Pmel117}$, PRAME, NY-ESO-1, cdc27, adenomatous polyposis coli protein (APC), fodrin, Connexin 37, Ig-idiotype, p15, gp75, GM2 ganglioside, GD2 ganglioside, human papilloma virus proteins, Smad family of tumor antigens, Imp-1, P1A, EBV-encoded nuclear antigen (EBNA)-1, brain glycogen phosphorylase, SSX-1, SSX-2 (HOM-MEL-40), SSX-1, SSX-4, SSX-5, SCP-1 and CT-7, and c-erbB-2.

298. The composition of claim 290, wherein the agent of Formula I is formulated for administration at a dose of greater than 10^{-8}M.

299. The composition of claim 273 or 290, wherein the cancer antigen is a gene or gene product thereof that has undergone chromosomal alteration.

300. The composition of claim 299, wherein the gene product is a RNA or protein gene product.

301. The composition of claim 299, wherein the gene or gene product thereof that has undergone chromosomal alteration is selected from the group consisting of gene or gene products associated with activation of quiescent genes, and gene or gene products associated with a novel fusion gene and protein.

302. The composition of claim 301, wherein the gene or gene products associated with activation of quiescent genes is selected from the group consisting of *BCL-1 and IgH; BCL-2 and IgH; BCL-6, TAL-1 and TCRδ or SIL* ; *c-MYC and IgH or IgL; MUN/IRF4 and IgH;* and *PAX-5 (BSAP)*

303. The composition of claim 301, wherein the gene or gene products associated with a novel fusion gene and protein is selected from the group consisting of *RARα, PML, PLZF, NPM or NuMA, BCR and ABL, MLL (HRX), E2A and PBX or HLF, NPM, ALK*, and *NPM, MLF-1.*

304. The composition of claim 273 or 290, wherein the cancer antigen is a tissue- or lineage-specific antigen.

305. The composition of claim 304, wherein the tissue- or lineage-specific antigen is a cell surface protein, epidermal growth factor receptor, cell-associated protein, or a secreted protein.

306. The composition of claim 305, wherein the cell surface protein is selected from the group consisting of CD20, CD22, CD52, CD33, CD10 (gp100), CD3/T-cell receptor (TCR), CD79/B-cell receptor (BCR), CD26, Human leukocyte antigen (HLA)-DR, HLA-DP, and HLA-DQ, RCAS1, and Prostate specific membrane antigen.

307. The composition of claim 305, wherein the epidermal growth factor receptor is selected from the group consisting of EGFR (HER1 or erbB1) and EGFRvIII, erbB2 (HER2 or HER2/neu), erbB3 (HER3), and erbB4 (HER4).

308. The composition of claim 305, wherein the cell-associated protein is selected from the group consisting of Tyrosinase, Melan-A/MART-1, tyrosinase related protein (TRP)-1/gp75 , Polymorphic epithelial mucin (PEM), and Human epithelial mucin (MUC1).

309. The composition of claim 305, wherein the secreted protein is selected from the group consisting of Monoclonal immunoglobulin, Immunoglobulin light chains, α-fetoprotein, Kallikreins 6 and 10, Gastrin-releasing peptide/bombesin, and Prostate specific antigen.

310. The composition of claim 273 or 290, wherein the cancer antigen is a cancer testis (CT) antigen.

311. The composition of claim 310, wherein the cancer testis (CT) antigen is selected from the group consisting of MAGE, MAGE-A1, -A3, -A6, -A12, MAGE-3, BAGE, GAGE, GAGE -1, -2, -3, -4, -5, -6, -7, and -8, HAGE, LAGE-1, NY-ESO-1, RAGE, RAGE-1, -2, -4, SSX, SSX-1, -2, -3, -4, -5, -6, -7, -8, -9, HOM-TES-14/SCP-1, HOM-TES-85, HOM-MEL-40, and PRAME.

312. The composition of claim 273 or 290, wherein the cancer antigen is a non-tissue or non-lineage specific antigen.

313. The composition of claim 312, wherein the non-tissue or non-lineage specific antigen is a carcinoembryonic antigen family member.

314. The composition of claim 313, wherein the carcinoembryonic antigen family member is selected from the group consisting of CD66a, CD66b, CD66c, CD66d and CD66e.

315. The composition of claim 273 or 290, wherein the cancer antigen is a viral protein.

316. The composition of claim 315, wherein the viral protein is selected from the group consisting of Human papilloma virus protein and EBV-encoded nuclear antigen (EBNA)-1.

317. The composition of claim 273 or 290, wherein the cancer antigen is an antigen that is mutated or aberrantly expressed in a cancer.

318. The composition of claim 317, wherein the antigen that is mutated or aberrantly expressed in a cancer is CDK4 or beta-catenin.

319. The composition of claim 273 or 290, wherein the cancer antigen is selected from the group consisting of VEGF, Anti-idiotypic mAb (GD3 ganglioside mimic), CD20, CD52, Anti-idiotypic mAb (CEA mimic), ERBB2, EGFR, CD22, ERBB2 X CD65 (fcγRI), CD33, EpCam, and PEM.

320. A composition comprising
an effective amount of an agent of Formula I and a microbial antigen,
wherein the agent of Formula I is formulated for administration at a dose of greater than 10^{-8}M.

321. The composition of claim 320, wherein the effective amount is an amount to treat or prevent an infectious disease.

322. The composition of claim 320, wherein the microbial antigen is a peptide antigen.

323. The composition of claim 320, wherein the microbial antigen is a lipid antigen.

324. The composition of claim 320, wherein the microbial antigen is selected from the group consisting of a bacterial antigen, a mycobacterial antigen, a viral antigen, a fungal antigen, and a parasitic antigen.

325. The composition of claim 324, wherein the bacterial antigen is derived from a bacterial species selected from the group consisting of E. coli, Staphylococcal, Streptococcal, Pseudomonas, Clostridium difficile, Legionella, Pneumococcus, Haemophilus, Klebsiella, Enterobacter, Citrobacter, Neisseria, Shigella, Salmonella, Listeria, Pasteurella, Streptobacillus, Spirillum, Treponema,

Actinomyces, Borrelia, Corynebacterium, Nocardia, Gardnerella, Campylobacter, Spirochaeta, Proteus, Bacteriodes, H. pylori, and anthrax.

326. The composition of claim 324, wherein the viral antigen is derived from a viral species selected from the group consisting of HIV, Herpes simplex virus 1, Herpes simplex virus 2, cytomegalovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, human papilloma virus, Epstein Barr virus, rotavirus, adenovirus, influenza A virus, respiratory syncytial virus, varicella-zoster virus, small pox, monkey pox and SARS.

327. The composition of claim 324, wherein the fungal antigen is derived from a fungal species that causes an infection selected from the group consisting of candidiasis, ringworm, histoplasmosis, blastomycosis, paracoccidioidomycosis, crytococcosis, aspergillosis, chromomycosis, mycetoma infections, pseudallescheriasis, and tinea versicolor infection.

328. The composition of claim 324, wherein the parasitic antigen is derived from a parasite species selected from the group consisting of amebiasis, Trypanosoma cruzi, Fascioliasis, Leishmaniasis, Plasmodium, Onchocerciasis, Paragonimiasis, Trypanosoma brucei, Pneumocystis, Trichomonas vaginalis, Taenia, Hymenolepsis, Echinococcus, Schistosomiasis, neurocysticercosis, Necator americanus, and Trichuris trichuria.

329. The composition of claim 324, wherein the mycobacterial antigen is derived from a mycobacterial species selected from the group consisting of M. tuberculosis and M. leprae.

330. The composition of claim 261, 290 or 320, wherein the agent of Formula I is an agent of Formula II.

331. The composition of claim 261, 290 or 320, wherein the agent of Formula I is an agent of Formula III.

332. The composition of claim 261, 290 or 320, wherein the agent of Formula I is selected from the group consisting of L-Val-L-boroPro, L-Met-L-boroPro, and L-Ile-L-boroPro.

333. The composition of claim 261, 290 or 320, wherein the agent of Formula I is in a cyclic form.

334. The method of claim 18, 90, 102, 177, 195 or 197, wherein the cancer is a refractory cancer.

335. The method of claim 334, wherein the refractory cancer is selected from the group consisting of leukemia, melanoma, renal cell carcinomas, colon cancer, liver (hepatic) cancer, pancreatic cancer, Non-Hodgkin's lymphoma and lung cancer. .

336. The method of claim 25, wherein the cancer is a refractory cancer.

337. The method of claim 336, wherein the refractory cancer is selected from the group consisting of leukemia, melanoma, renal cell carcinoma, colon cancer, liver (hepatic) cancer, pancreatic cancer, Non-Hodgkin's lymphoma and lung cancer. .

338. The method of claim 1, 18, 24, 81, 90, 97, 168, 177, 182, 184, 188, 191, 195, 197 or 210, wherein the agent of Formula I is at least 96% pure L-isomer.

339. The composition of claim 261, 290, 320, wherein the agent of Formula I is at least 96% pure L-isomer.